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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*file copy*

Application No.

09/549,970

Applicant(s)

RAVKIN ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31-37 and 41-45 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 9. 6) ☐ Other: _____

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Detailed Action

Status of the Application

Receipt is acknowledged of a response to an office action with amendment on 30 April 2002 (Paper No. 11).

Status of the Claims

Claims 26-45 are pending in the present application. Claims 30 and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 26-29, 31-37, and 41-45 are pending and examined on their merits.

Objections to the Claims

1. Claim 36 is objected to because it appears to be missing the word “a” before “*confocal optics structure*.”

Claims Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 26 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (New Matter).

New claim 26 recites an array device comprising a surface and at least two carriers, "*the at least two carriers being arbitrarily distributed on the surface.*" Applicants point out figures 4 and 5 and pages 16 and 17 of the specification as providing support for the new claim. The examiner does not find support for the "*arbitrary*" distribution of carriers on a support. The parts of the specification cited by applicants appear to support "*random*" distribution, however.

New claim 42 recites that "*each carrier has an analyte area and a code display area.*" New claim 43 recites that "*the analyte area and code area substantially coincide.*" New claim 44 recites that "*the analyte area and code at least partially overlap with each other.*" Applicants direct the examiner to figures 10 and 11 in the specification for support. The figures and their description on pages 18-19 of the specification do not appear to support the limitations recited in these new claims.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-29, 31-37, and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 26, it is not clear if the term "*arbitrarily*" is intended to mean "randomly" or if the carriers can be placed at specific locations in a segregated manner so long as their placement is "*arbitrary*." Clarification is requested.

B. In claim 26, the metes and bound of "*distributed on the surface*" are not clear. It is not clear if the carriers are in some way attached to the surface by covalent or non-covalent interactions, if the carriers are placed within wells, if the carriers are merely in contact with the surface and held in place by gravity, if the carriers can all be in a test tube, for example, or if the carriers can be in motion and passing along the surface. Clarification is requested.

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C. In claims 26-29, 31-37, and 41-45, it is not clear what statutory class of invention applicants are seeking to patent. “*An array device*” is not a statutory class of invention such as an apparatus or composition, for example. The word “*device*” appears to indicate an apparatus, while the inclusion of carriers and analytes appears to correspond to a composition.

D. In claim 29, the metes and bound of “*optically identifiable marks*” are not clear. It is not clear for example, if a “*mark*” can be, for example, a particular frequency of light such that two “*marks*” (i.e. two different frequencies of light) could originate from the same physical space on a carrier.

E. In claim 30, the metes and bounds of “*fiber optic components*” are not clear. The specification does not provide one of ordinary skill in the art a means for determining what applicants consider to be “*components*” of a fiber optic fiber, a fiber optic assay apparatus, a fiber optic bundle, etc. It is not clear, for example, if a wave guide or a material used in the manufacture of a wave guide would be considered to be a “*fiber optic component*.”

F. In claim 31, the phrase “*the carriers include nanocrystals*” could be interpreted to mean that some of the carriers are nanocrystals and some are not or that all of the carriers contain nanocrystals, for example. Clarification with respect to the phrase “*the carriers include nanocrystals*” is requested.

G. Claim 34 recites the limitation “*the at least one **digital image***” in line 2 (emphasis added). There is insufficient antecedent basis for this limitation in the claim.

H. In claims 35 and 36, it is not clear if “*includes*” is to be interpreted as “*comprises*” or if the claims are to be interpreted to recite that microscopes and confocal optics structures.

I. In claim 42, the metes and bounds of “*analyte area*” and “*code display area*” are not clear. The base claim from which these claims depend recites carriers having a detectable code and carrying analytes. It appears that analyte and code areas would be inherent in claim 26 since both analyte and code are present on each carrier. Clarification is requested.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 26-29, 32, and 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nova et al. U.S. Patent No. 5,741,462 April 1998.

The Nova et al. reference discloses remotely programmable matrices for use in immunological, analytical, chemical, and biological assays (abstract). Column 4, lines 52-61, discloses that the matrix material may be glass or a polymer, for example, and may be in the form of a continuous surface (as a glass tube or microtiter plate) or particulates. Column 5, lines 10-35, discloses a data storage device with encoded information that identifies molecules or biological particles that are in close proximity to the matrix and that the device may include a support matrix disposed on an outer surface of a shell for retaining molecules or biological particles (i.e. the molecules or biological particles may be attached to the recording devices). Column 6, lines 1-4, discloses that the recording devices may be placed in or on the matrix. Column 11, lines 7-38, discloses that the encoding device may include an electromagnetic tag (including visible light). Column 19, lines 1-12, discloses that the recording devices may be optically programmable read/write devices. Column 25, lines 48-65, discloses an optical encoding system that uses different wavelengths (colors) of light. Column 30, lines 18-23, discloses an array of memories (devices) embedded in a matrix (i.e. arbitrarily distributed on a surface) with different antibodies linked to different memories. Accordingly, the Nova et al. reference anticipates present claims 26-28, 32, and 41-44.

Column 25, lines 53-59, discloses that multiple spectral holes can be superimposed on a programmable information device (i.e. multiple wavelengths of light may pass through), anticipating present claim 29. Column 26, lines 1-23 discloses the use of optical disks, which require a flattened tube and at least one flat surface for alignment with an optical writing device, anticipating present claim 45.

5. Claims 26-28, 31, 32, 35, 37, and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al. U.S. Patent No. 6,114,038 September 2000.

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The Castro et al. reference discloses compositions comprising water soluble nanocrystals (carriers) and their use in detecting substrates that bind to affinity ligands (analytes) attached to the surfaces of the nanocrystals (abstract). Column 13, lines 47-67, discloses the cited nanocrystals are generated to have different uniform sizes that cause them to emit different colors of light in response to a stimulus. Consequently, the ligand-coated nanocrystals can be used to assay for multiple substrates (ligands) simultaneously using, for example, immunofluorescent staining on a glass slide or flow cytometry. Column 14, lines 1-26, discloses the placement of a mixture containing cells and ligand-coated nanocrystals onto a glass slide (arbitrarily distributing the nanocrystals on a surface). The mixture was examined using a fluorescence microscope. While not explicitly stated in the cited reference, one of ordinary skill in the art would immediately have envisaged the capture of the image produced by the microscope and using that image to interpret the experiment. Column 4, line 15 discloses that the affinity ligand (analyte) may be a nucleic acid. Accordingly, the Castro et al. reference anticipates present claims 26-28, 31, 35, 37, and 41-44.

Claims Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26-29, 32-37, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. U.S. Patent No. 5,741,462 April 1998.

The Nova et al. reference teaches remotely programmable matrices for use in immunological, analytical, chemical, and biological assays (abstract). The matrix material may be glass or a polymer, for example, and may be in the form of a continuous surface (as a glass tube or microtiter plate) or particulates. The reference teaches a data storage device with encoded information that identifies molecules or biological particles that are in close proximity

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to the matrix and that the device may include a support matrix disposed on an outer surface of a shell for retaining molecules or biological particles (i.e. the molecules or biological particles may be attached to the recording devices). The recording devices may be placed in or on the matrix and the encoding device may include an electromagnetic tag (including visible light). The recording devices may be optically programmable read/write devices that use different wavelengths (colors) of light. Multiple spectral holes can be superimposed on a programmable information device. Column 30, lines 18-23, teaches an array of memories (devices) embedded in a matrix with different antibodies linked to different memories.

The Nova et al. reference does not specifically teach using a CCDD camera or acquiring digital images, the use of a microscope or confocal optics. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to select from a variety of optical reading devices such as a CCD camera for obtaining digital images or a microscope with confocal optics. One would have been motivated to do so because digital cameras would produce digital images for computer processing and confocal microscopes would be useful for enlarging images of small assay areas. One would have had a reasonable expectation for success because digital image capture and the use of confocal microscopes was routine in the art.

7. Claims 26-28, 31-37, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. U.S. Patent No. 6,114,038 September 2000.

The Castro et al. reference teaches compositions comprising water soluble nanocrystals (carriers) and their use in detecting substrates that bind to affinity ligands (analytes) attached to the surfaces of the nanocrystals (abstract). The nanocrystals are generated to have different uniform sizes that cause them to emit different colors of light in response to a stimulus and ligand-coated nanocrystals can be used to assay for multiple substrates (ligands) simultaneously using, for example, immunofluorescent staining on a glass slide or flow cytometry. Column 14, lines 1-26, teaches the placement of a mixture containing cells and ligand-coated nanocrystals onto a glass slide (arbitrarily distributing the nanocrystals on a surface). The mixture was examined using a fluorescence microscope. While not explicitly stated in the cited reference, one of ordinary skill in the art would immediately have envisaged the capture of the image

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produced by the microscope and using that image to interpret the experiment. Column 4, line 15 teaches that the affinity ligand (analyte) may be a nucleic acid.

The Castro et al. reference does not explicitly teach the use of a CCD camera, acquiring a digital image, or using a confocal optics structure. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to select from a variety of optical reading devices such as a CCD camera for obtaining digital images or a microscope with confocal optics. One would have been motivated to do so because digital cameras would produce digital images for computer processing and confocal microscopes would be useful for enlarging images of small assay areas. One would have had a reasonable expectation for success because digital image capture and the use of confocal microscopes was routine in the art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
23 July 2002

BENNETT CELSA
PRIMARY EXAMINER

